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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/632,271

07/31/2003

Michael P. Whitman

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10/04/2007

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EXAMINER

HOUSTON, ELIZABETH

ART UNIT

PAPER NUMBER

3731

NOTIFICATION DATE

DELIVERY MODE

10/04/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@kenyon.com

Office Action Summary

Application No.

10/632,271

Applicant(s)

WHITMAN ET AL.

Examiner

Elizabeth Houston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 12, 14-20, 28, 31-33 and 39-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 12, 14-20, 28, 31-33 and 39-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of species b (including figures 3A to 3G) in the reply filed on 07/16/07 is acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Claims 39-43 are rejected under 35 U.S.C. 112, first paragraph**, because the specification, while being enabling for "a surgical instrument inserted into a tubular member and advanced distally therethrough" (spec page 6, line 15), does not reasonably provide enablement for "the tubular member having a therein a surgical stapler apparatus" (claim 39). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Regarding a combination of an orifice introducer and a surgical stapler, the specification offers no directives on the use of a stapler with this particular invention. The specification sites the procedure of introducing a surgical stapler into a patient in the background section, but does not disclose introducing the stapler through an introducer. The detailed description (page 6, line 15-20) states that a surgical instrument can be inserted into the tubular member but provides no further instruction given in the specification regarding how the stapler is inserted or coupled to or used with the introducer. Additionally, there are no drawings to

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depict the combination. The lack of details regarding the relationship of the introducer and the stapler makes the combination unclear.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claims 39-43 are rejected under 35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 39 is indefinite since the preamble is claiming "an orifice introducer device", but the scope of the claim incorporates an introducer and a stapler. It is unclear whether applicant intends to positively claim the stapler or intends to claim an introducer that is capable of receiving a stapler. Until the claims are rectified, examiner will address both scenarios in the rejections.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 11, 12, 14-17, 20, 28, 31-33 and 39-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Dormia et al (USPN 5,176,127).**

8. Dormia discloses an introducer (Fig. 3) comprising a tubular member (1) having a distal end (14, 6); a distal portion (9) having a proximal end configured to be detachably

secured to the distal end of the tubular member [(Col 3, lines 63-67) alternatively: (for example in Fig. 1, the expansion of the strips 16, against the inner surface of the tubular member will secure the distal tip to the tubular member), the distal portion being selectively detachable when the orifice introducer device is positioned in the orifice (Col 4, lines 51-60), wherein, when detached from the distal end of the tubular member, the proximal end of the distal portion contracts so as to have a smaller diameter than the tubular member (Fig. 3). The distal end (19) of the distal portion has a smaller diameter than the tubular member, when secured to the distal end of the tubular member (Fig. 1). The proximal end of the distal portion includes an annular groove (18) configured to detachably secure the distal end of the tubular member (as in Fig. 1 and stated above). A tubular insertion device is configured to be inserted through the tubular member (10). The tubular insertion device is configured to detach the distal portion from the tubular member when inserted through the tubular member (The distal portion is detached when the tubular member is inserted up until the point it reaches member (18), for example Fig. 3). A recovery device (7) for withdrawing the distal portion through the tubular member when the distal portion has been detached from the tubular member. The introducer is configured to introduce a surgical device that is capable of being a surgical stapler (*in the event that applicant did not intend to positively claim the surgical stapler of claim 39*) (Col 1, lines 51-55). Dormia further discloses a method of using the device that includes detachably securing a proximal end of a distal portion to the distal end of the tubular member [(Col 3, lines 63-67) and alternatively (Fig. 1, as described above)], inserting the distal end into an orifice (Col 4, line 43), selectively detaching the

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distal portion [(Col 4, line 57-60) and alternatively (Fig. 3)], the distal portion contracting to have a diameter smaller than the tubular member (compare Figs. 1 and 3) and withdrawing the distal portion through the tubular member (Col 4, Lines 57-60). The step of selective detaching (in other words, selecting to detach or selecting to not detach the distal tip) includes inserting a tubular insertion device (10) for contacting the inner wall of the distal portion (18) (Fig. 1). The distal tip is conical and tapered.

9. Claims 11, 12, 14 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Dotolo (US 5,931,776).

10. Dotolo discloses an orifice introducer device comprising: a tubular member (10) having a distal end; a distal portion (12) having a proximal end configured to be detachably secured to the distal end of the tubular member (Col 2, Line 20-22), the distal portion being selectively detachable when the orifice introducer device is positioned in the orifice, wherein, when detached from the distal end of the tubular member, the proximal end of the distal portion contracts so as to have a smaller diameter than the tubular member (as tip 12 dissolves it will contract to have a smaller diameter). When secured to the distal end of the tubular member, a distal end of the distal portion has a smaller diameter than the tubular member. The proximal end of the distal portion includes an annular groove (16) configured to detachably secure the distal end of the tubular member. The introducer is *configured to (or capable of)* introduce a surgical device

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

In the case that applicant intended to positively claim the surgical stapler in claim 39 (see 112 2nd rejection above), the following applies.

12. Claims 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dormia (US 5,176,127) in view of Puskas (US 6,042,538).

13. Dormia discloses all the limitations of the invention substantially as claimed as stated above except for the surgical stapler. Dormia does disclose the insertion of electrically operated surgical appliances such as electrically driven scalpels.

14. Puskas discloses inserting instruments into an endoscope that include retractors, staplers, suction devices, and electric devices.

15. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a surgical stapler into the invention of Dormia in the place of an electrical scalpel since the two surgical devices were art recognized equivalents at the time of the invention was made. Additionally, it is well known in the art to use endoscopes as a guiding in device for surgical staplers.

16. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dormia (US 5,176,127).

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17. Dormia discloses the invention substantially as claimed as stated above.

However Dormas fails to disclose that the recovery device is a string. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to replace the tubular recovery device with a string because it would reduce the overall profile of the device. Applicant has not disclosed that the string provides an advantage, is used for a particular purpose or solves a stated problem. In fact, the instant disclosure describe this parameter as merely preferable and does not describe it as contributing any unexpected result to the introducer. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Response to Arguments

18. Applicant's arguments with respect to claim 11, 12, 14-20, 31-33 and 39-43 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

eh



ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

9/28/07